DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

November 5, 1999

Dear Medical Device Manufacturer:

On October 20, 1999, the Federal Communications Commission (FCC) released Public Notice DA 99-2244 (attached) requesting information from users of wireless medical telemetry equipment operating in the 450-460 MHz frequency range. The purpose of this letter is to inform you of the FCC Public Notice, encourage you to respond to the FCC, and to work with your customers to help provide the requested information.

Under Part 90 of Title 47 of the Code of Federal Regulations, wireless medical telemetry devices are allowed to operate as secondary users on channels offset 12.5 kHz from regularly assigned channels in the Private Land Mobile Radio Service (PLMRS) band between 450 MHz and 470 MHz. Preliminary information from an informal survey of users by the American Society of Healthcare Engineers suggests that more than one-half of the wireless medical telemetry equipment in use currently is operating in this frequency band. However, in 1995, FCC adopted rule changes to the PLMRS which were intended to increase the number of channels available for use by the primary licensed users in this band. These proposed changes could result in possible interference to wireless medical telemetry equipment currently operating in the 450-470 MHz band. For this reason, on August 11, 1995, the FCC placed a freeze on the filing of applications for high power operation in the 450-470 MHz band on the 12.5 kHz offset channels.

In the Public Notice, the FCC indicates that it may be possible to lift the freeze on applications for high power operation on the 12.5 kHz offset channels in the 450-460 MHz band. This decision is based on information available to the FCC which shows that the majority of the wireless medical telemetry equipment permitted to operate in the 450-470 MHz band actually operates at frequencies of 460-470 MHz. However, since wireless medical telemetry devices are allowed unlicensed operation anywhere within 450-470 MHz band, the FCC's information about users of wireless medical telemetry equipment operating in this band is incomplete. Hence, there is an urgent need to provide the FCC with information that will assist them to make an informed decision, and help prevent potentially serious interference problems with wireless medical telemetry devices.

If you are a manufacturer or distributor of wireless medical telemetry equipment that operates in the 450-460 MHz band, the Food and Drug Administration (FDA) encourages you to provide the FCC with the information as requested in the attached Public Notice. FDA also encourages you to help your healthcare customers respond to the FCC Notice.

Additional information can be found at the FCC's internet web site at www.fcc.gov. A copy of the Public Notice is available at www.fcc.gov/Bureaus/Engineering_Technology/Public_Notices/1999/da992244.doc.

If you have any questions regarding this issue, please contact Thinh X. Nguyen at (301) 443-8262, ext. 162.

Sincerely yours,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

PUBLIC NOTICE

Federal Communications Commission
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Washington, D.C. 20554

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DA 99-2244
Released: October 20, 1999

Office of Engineering and Technology Requests Information on Medical Telemetry Equipment Operating in the 450-460 MHz Band

The Office of Engineering and Technology is asking parties operating medical telemetry equipment in the 450-460 MHz band to assist the Commission by providing certain information on their operation. It is requested that users of wireless medical telemetry equipment operating in this band provide information on the numbers, types, locations, and frequencies of equipment presently in use. Parties are asked to submit this information to the Chief, Office of Engineering and Technology by January 31, 2000. The requested information will aid the Commission in determining whether it is feasible to lift the currently effective freeze on the filing of Part 90 applications for high-power operation in the 450-460 MHz band on the 12.5 kHz offset channels without adversely affecting existing medical telemetry operations.

Medical telemetry equipment is used in hospitals and health care facilities to transmit patient measurement data, such as pulse and respiration rates, to a nearby receiver. Part 90 of the Commission's rules permits medical telemetry equipment to operate on a secondary basis to land mobile users in the 450-470 MHz band. Hospitals and health care facilities holding a valid license to operate a radio station under Part 90 may operate medical telemetry equipment without any specific authorization from the Commission (see 47 C.F.R. § 90.267). As a consequence, the Commission does not have any records concerning the locations of medical telemetry operations in the 450-470 MHz band.

In 1995, the Commission adopted changes to Part 90 of the rules to allow more efficient use of the spectrum for land mobile services. The *Report and Order and Further Notice of Proposed Rule Making* in PR Docket 92-235, FCC 95-255, released June 23, 1995 <www.fcc.gov/Bureaus/Wireless/Orders/1995/> established a new channeling plan for private land mobile radio services (PLMRS). This *Order* adopted a channel spacing plan for PLMRS in the 450-470 MHz band based on 6.25 kHz.

Medical telemetry equipment operates in the 450-470 MHz band on channels offset 12.5 kHz from regularly assignable channels under the old channelization plan ("12.5 kHz offset channels"). The maximum operating power for this equipment is substantially less than that authorized for primary users of the band. The channel separation and low-power

operation minimize the possibility of interference received from, or caused to, primary users of the band. However, under the new channeling scheme, high-power primary users of the band would be able to operate on the same frequencies used for medical telemetry equipment. This could possibly result in interference to medical telemetry equipment. For this reason, on August 11, 1995, the Commission placed a freeze on the filing of applications for high power operation in the 450-470 MHz band on the 12.5 kHz offset channels. See the *Public Notice, "Freeze on the Filing of High Power Applications for 12.5 kHz Offset Channels in the 450-470 MHz Band,"* DA 95-1171, <www.fcc.gov/Bureaus/Wireless/Public_Notices/1995/da951771.txt>. The freeze remains in effect pending the development of a channel utilization plan that will protect low power operation on the 12.5 kHz offset channels.

The Commission expects medical telemetry equipment ultimately to migrate out of the PLMRS bands and into new bands allocated for medical telemetry. The Commission recently proposed rules to allocate frequencies where medical telemetry equipment can operate on a primary basis. See the *Notice of Proposed Rule Making* in ET Docket 99-255, FCC 99-182, released July 16, 1999 <www.fcc.gov/oet/dockets/et99-255/>. While this would be a long term solution to the problem of PLMRS interference to medical telemetry equipment, the Commission may be able take action in the near term to partially lift the freeze on high power applications on the offset channels.

The Commission's records of manufacturers' equipment authorizations show that the majority of medical telemetry equipment authorized for use under Part 90 (47 C.F.R. Part 90) is authorized only for the 460-470 MHz portion of the 450-470 MHz band. Further, prior to the radio service consolidation in the *Second Report and Order* in PR Docket 92-235, the only "Industrial Radio Services" spectrum available to hospitals and health care facilities were frequencies allocated to the old Business Radio Service. There were very few frequencies in the 450-460 MHz band allocated to that service. For these reasons, it may be possible to lift the freeze on applications for high power operation on the 12.5 kHz offset channels in the 450-460 MHz band. Before doing so, however, the Commission wants to ensure that interference will not be caused to medical telemetry equipment in that band. Accordingly, we are requesting that parties operating medical telemetry equipment in the 450-460 MHz band provide certain information on their operation to the Commission's Office of Engineering and Technology. The filing of this information is strictly voluntary, but parties should note that providing it could help prevent serious interference problems in the future. Parties may want to check with the manufacturer of their equipment to determine the operating frequency.

We are asking for the following information:

1. The name and address of the institution operating the equipment, along with the name, telephone number and e-mail address of a contact person there.
2. The number and types of devices being operated in the 450-460 MHz band, including the make, model number, FCC identification number, age, and type of equipment (e.g., heart rate monitor), and total number of channels of medical telemetry used in the facility.

3. The operating frequencies and RF output power of these devices.
4. The geographic coordinates of the institution, if known.
5. Whether the equipment could be re-tuned to operate in the 460-470 MHz band and, if so, the time period required for such re-tuning and the estimated expense of re-tuning that would be incurred by the institution operating the equipment.

Parties are asked to respond to the following address by January 31, 2000.

Chief, Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

For further information about this notice, please contact Hugh L. Van Tuyl at: (202) 418-7506, email: hvantuyl@fcc.gov.